PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	10/799,297
Applicant	:	Donald E. Brodnick
Filed	:	03/12/2004
Title	:	Respiration Monitoring System And Method
TC/A.U.	:	3735
Examiner	:	Karen E. Toth
Docket No.	:	139341-1 (5024-00079)
Confirmation No.		8184

CERTIFICATE OF EFS WEB FILING

I hereby certify that this correspondence is being electronically filed on this 4th day of September, 2007.

Roni Haupt 9-4-07

Roni Haupt Date

AMENDMENT

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper responds to an Office Action mailed June 1, 2007. The three month response deadline expired on September 1, 2007, which was a Saturday. The extended three month deadline is September 4, 2007. Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 9 of this paper.

Listing of Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A patient monitoring system comprising:

a plurality of inputs, the plurality of inputs being configured to be coupled to a plurality of electrodes including first, second and third electrodes;

a processing circuit coupled to the plurality of inputs, the processing circuit being configured to process signals from the plurality of electrodes to produce a respiration parameter for a patient, the processing circuit having a first mode of operation in which the processing circuit produces the respiration parameter by measuring impedance between the first and second electrodes and uses the third electrode to eliminate or reduce a common mode voltage present in the signals obtained from the first and second electrodes, and the processing circuit having a second mode of operation in which the processing circuit produces the respiration parameter by measuring impedance between the third electrode and an additional one of the plurality of electrodes.

2. (Original) The system of claim 1, wherein the third electrode is connected to the processing circuit by the RL leadwire

3. (Original) The system of claim 1, wherein the processing circuit is capable of operating in the first and second modes of operation simultaneously.

4. (Original) The system of claim 1, wherein the additional one of the plurality of electrodes is one of the first and second electrodes.

5. (Original) The system of claim 1, wherein the respiration parameter is respiration rate.

6. (Original) The system of claim 1, wherein the first and second electrodes are attached to a human having a abdomen and at least one lung and further wherein the first electrode and second electrodes are attached to the human such that a straight line extending from the first electrode to the second electrode passes through a lower portion of the lungs adjacent to the abdomen.

7. (Original) The system of claim 6, wherein the straight line substantially avoids passing through an aorta, heart, neck, or any shoulder of the patient.

8. (Original) The system of claim 6, wherein the first electrode is attached to at least a right or left leg.

9. (Original) The system of claim 8, wherein the first electrode is attached to the left leg at a LL location or to the right leg at a RL location.

10. (Original) The system of claim 6, wherein the second electrode is attached to an opposite side of abdomen as the first electrode and further wherein the second electrode is located below an armpit.

11. (Original) The system of claim 1, wherein the second electrode is attached to an electrode location selected from the group consisting of the V5R, HV5R, V6R, HV6R, V5, HV5, V6, and HV6 electrode locations.

12. (Original) The system of claim 11, wherein the second electrode is attached to an electrode location selected from the group consisting of the V5R V6R, HV5R and HV6R electrode locations.

13. (Currently amended) An apparatus for monitoring the respiration rate of a human having a thorax and at least one lung, the apparatus comprising:

a first input configured to be connected to a first electrode attached to the thorax;

a second input configured to be connected to a second electrode attached to an opposite side of the thorax as the first electrode, and such that a first conductive path extends through a lower portion of the lungs between the first and second electrodes~~inputs~~;

a third input configured to be connected to a third electrode, the third electrode being a RL electrode that is configured to both eliminate or reduce a common mode voltage present in signals obtained from the first and second electrodes and provide a second conductive path with one of the first or second electrodes; and

a processing circuit configured to detect fluctuations in impedance in the first or second conductive paths, and derive a respiration signal at least from the fluctuations.

14. (Original) The apparatus of claim 13, wherein the processing circuit is also an ECG monitoring circuit that is configured to use a signal from the third electrode as a voltage reference signal in the ECG monitoring circuit.

15. (Original) The apparatus of claim 13, wherein the processing circuit is configured to be coupled to the first electrode to at least a right or a left leg.

16. (Original) The apparatus of claim 15, wherein the processing circuit is configured to be coupled to the first electrode at the LL location or to the right leg at the RL location.

17. (Original) The apparatus of claim 13, wherein the processing circuit is configured to be coupled to the second electrode at the opposite side of thorax below the armpit.

18. (Original) The apparatus of claim 12, wherein the processing circuit is configured

to be coupled to the second electrode at an electrode location selected from the group consisting of the V5R, HV5R, V6R, HV6R, V5, HV5, V6, and HV6 electrode locations.

19. (Original) The apparatus of claim 18, wherein the processing circuit is configured to be coupled to the second electrode at an electrode location selected from the group consisting of the V5R, HV5R, V6R, and HV6R electrode locations.

20. (Original) The apparatus of claim 13, wherein the processing circuit includes an electronic display screen, and further wherein the processing circuit is configured to display the respiration signal on the electronic display screen as a respiration rate numeric value.

21. (Original) The apparatus of claim 20, wherein the processing circuit is configured to display the respiration signal as a trace.

22. (Original) The apparatus of claim 21, wherein the processing circuit is configured to display the trace on the electronic display screen.

23. (Cancelled)

24. (Original) A patient monitor comprising:

an operator input device;

a plurality of signal inputs, the plurality of signal inputs being configured to receive signals from electrodes attached to a patient;

a processing circuit, the processing circuit being configured to process the signals received from the electrodes to generate a Lead I signal, a Lead II signal, and an abdominal respiration lead signal;

a display, the display being configured to display options for selection by the operator using the operator input device, the options including an option to display a parameter associated with the abdominal respiration lead signal.

25. (Original) A method of monitoring the respiration rate of a human having an abdomen and at least one lung, the method comprising the steps of:

detecting fluctuations in impedance in a conductive path between first and second electrodes and using a third electrode to eliminate or reduce a common mode voltage present in signals obtained from the first and second electrode in a first mode of operation of a processing circuit, the first electrode and second electrode being attached to the human such that a straight line extending from the first electrode to the second electrode passes through a lower portion of the lungs adjacent to the abdomen;

detecting fluctuations in impedance in a conductive path between the third electrode and one of the first and second electrodes in a second mode of operation of the processing circuit; and

deriving a respiration parameter based at least on the fluctuations.

26. (Original) A system for monitoring the respiration rate of a human having a thorax and at least one lung, the apparatus comprising:

a first electrode ~~means~~ for sensing body impedance, the first electrode being configured to be fixed to the thorax on the left leg at a LL location or on the right leg at a RL location;

a second electrode ~~means~~ for sensing body impedance and configured to be fixed below the armpit on ~~to~~ an opposite side of the thorax as the first electrode ~~means~~ for sensing body impedance to thereby define a conductive path extending through a lower portion of the lungs between the first and second electrodes ~~means~~ for sensing impedance;

a third electrode ~~means~~ for eliminating or reducing a common mode voltage present in signals obtained from the first and second means~~, the third means being a RL electrode~~; and

a means for monitoring respiration configured to detect fluctuations in impedance in the conductive path, and to derive a respiration signal at least from said fluctuations, said monitoring means being coupled to the first and second electrodes ~~means for sensing~~ and coupled via the electrodes ~~means for sensing~~ to the human.

27. (Currently amended) The system of claim 26, wherein the monitoring means is an ECG monitoring circuit that is configured to use a signal from the third electrode ~~means~~ for sensing as a voltage reference signal in the ECG monitoring circuit.

28. (Cancelled)

29. (Cancelled)

30. (Cancelled)

31. (Currently amended) The system of claim 26, wherein the monitoring means is configured to be coupled to the second electrode ~~means~~ for sensing at an electrode location selected from the group consisting of the V5R, HV5R, V6R, HV6R, V5, HV5, V6, and HV6 electrode locations.

32. (Currently amended) The system of claim 31, wherein the monitoring means is configured to be coupled to the second electrode ~~means~~ for sensing at an electrode location selected from the group consisting of the V5R, HV5R, V6R, and HV6R electrode locations.

33. (Original) The system of claim 26, wherein the monitoring means includes an electronic display screen, and further wherein the monitoring means is configured to display the respiration signal on the electronic display screen as a respiration rate numeric value.

34. (Original) The system of claim 33, wherein the monitoring means is configured to display the respiration signal as a trace.

35. (Original) The system of claim 34, wherein the monitoring means is configured to display the trace on the electronic display screen.

36. (Original) The system of claim 26 further comprising a hospital information system, and wherein the monitoring means is coupled to the hospital information system to make information derived from the respiration signal available on the hospital information system.

REMARKS

In the Office Action, the Examiner initially objected to the oath or declaration originally filed by the applicant. Specifically, the Examiner indicated that the original oath included the statement that the applicant acknowledged a duty to disclose information "material to the examination" when the declaration required the phrase to state that information is being disclosed that is "material to patentability". A substitute declaration executed by both of the inventors indicating that the information submitted to the USPTO was all the information known by the inventors to be "material to patentability" is submitted herewith.

In the Office Action, the Examiner indicated that claim 1-12, 18, 19, 24 and 25 were allowed over the prior art identified by the Examiner. The applicant hereby acknowledges and appreciates such finding by the Examiner.

In the Office Action, claim 23 was rejected under 35 USC §102(b) as being anticipated by the Kearns U.S. Patent No. 4,387,722. By the present response, claim 23 has been cancelled from the present application such that the rejection under §102(b) has been rendered moot.

In the Office Action, claims13-17, 20-22 and 26-35 were rejected under 35 USC §103(a) as being anticipated by the Kearns '722 patent in combination with the Rohde U.S. Patent No. 5,876,351. The applicant assumes the Examiner intended to reject these claims based upon the combination of the Kearns '722 and Rohde '351 references under §103, rather than §102(b) as set forth on page 3 of the Office Action.

Reconsideration of the above claim rejections is respectfully requested in view of the foregoing claim amendments, as well as the following arguments for allowance.

Claim 13

By the present response, independent claim 13 has been amended to indicate that the apparatus includes a third electrode that is configured to both eliminate or reduce a common mode voltage present in signals obtained from the first and second electrodes

and to provide a second conductive path with one of the first and second electrodes. Claim 13 has also been amended to indicate that the processing circuit is configured to detect fluctuations and impedance in the first or second conductive path and to derive a respiration signal from the fluctuation.

In the reasons for allowance included in the outstanding Office Action, the Examiner indicated that the second conductive path between one of the first and second electrodes and the third electrode was not taught or suggested by any of the references cited by the Examiner. Based upon these comments made by the Examiner in the Office Action and the amendments made to claim 13, independent claim 13 is now believed to be in condition for allowance.

Claims 14-17, 20-22 depend directly or indirectly from claim 13 and are thus also believed to be allowable.

Claim 26

By the present response, independent claim 26 has been amended to indicate that the first electrode is configured to be fixed onto the thorax of a human on the left leg at the LL location or on the right leg at the RL location. Further, claim 26 requires the second electrode to be fixed below the armpit on an opposite side of the thorax as the first electrode for sensing body impedance and to thereby define a conductive path extending through a lower portion of the lungs between the first and second electrodes for sensing impedance. Claim 26 further requires a means for monitoring respiration that is configured to detect fluctuations in impedance in the conductive path between the first and second electrodes. This amendment generally combines the subject matter of original claims 26, 28, 29 and 30.

As taught in the specification of the present application, the position of the first and second electrodes is selected as described such that the conductive path extends across the thorax and through a lower portion of the lungs. This impedance path is particularly desirable to monitor the respiration rate of a patient when the patient is using

abdominal breathing, such as when the patient is unconscious. Since the conductive path passes over the lower portion of the lungs, this conductive path is an improvement over prior sensing techniques that utilize electrode placement across the upper portion of a patient's lungs.

In the Kearns '722 reference cited by the Examiner, the disclosure teaches the bipolar configuration of a set of electrodes E1 and E2 where each of the electrodes are placed over the sixth intercostals space on opposite sides of the thorax. (See col. 13, lines 29-43.) Although the electrodes E1 and E2 are positioned generally beneath the armpit over the six intercostals space, these electrodes are generally aligned with each other on opposite sides of the thorax. Thus, the first and second electrodes in the Kearns '722 reference do not teach a conductive path that extends through a lower portion of the lungs, as is required by claim 26. Specifically, claim 26 requires the first electrode to be fixed to the thorax on either the left leg or the right leg and the second electrode to be fixed generally below the armpit on the opposite side of the thorax. Clearly, the Kearns reference does not teach this location of the first and second electrodes or the conductive path created by the placement of these electrodes.

In rejecting claims 28-30, which have generally been incorporated into claim 26, the Examiner relied upon the Rohde '351 reference to show that a means for sensing may be connected to the patient's leg. As the Examiner correctly indicated, the placement of an ECG electrode on the patient's right or left leg is well known to one of ordinary skill in the art. However, independent claim 26 requires the placement of the first electrode on the right or left leg of the patient to be part of a conductive path that is utilized for monitoring the respiration rate of a human. The positioning of one of the two electrodes that defines the conductive path for sensing body impedance to monitor respiration rate on the leg is not taught or suggested by either the Rohde '351 or Kearns '722 references relied upon by the Examiner.

As described previously, the Kearns '722 reference teaches that both of the electrodes E1 and E2 are disposed over the sixth intercostals space. Thus, both the E1

and E2 electrodes are positioned under the armpits on the thorax. There is no teaching or suggestion in the Kearns '722 reference of utilizing the left leg location or the right leg location as part of the conductive path for respiration rate monitoring. Instead, the Kearns '722 reference teaches what is the known measurement option, namely positioning the first and second electrodes across the chest of the patient, as described in ¶ [0006] of the present application.

Likewise, although the Rohde '351 reference shows positioning an ECG electrode on one leg of a patient, there is no teaching or suggestion of utilizing an electrode placed on a leg of a patient to define one half of a conductive path that is utilized for monitoring the respiration rate of a human, as is required by claim 26.

Since neither of the references cited by the Examiner, either alone or in combination, teach the specific positioning of the first and second electrodes to define the conductive path as required by claim 26, independent claim 26 is allowable over the combination of references cited.

Claims 27, 31-36 depend directly or indirectly from claim 26 and are also believed to be allowable based upon the above arguments for allowance, as well as in view of the subject matter of each claim.

Conclusion

Based upon the Examiner's previous comments in the Office Action, claims 1-12, 18, 19, 24 and 25 have been allowed. Based upon the above arguments for allowance and claim amendments, claims 13-17, 20-22, 26-27 and 31-36 are also believed to be in condition for allowance.

The Examiner is invited to contact the applicant's undersigned attorney with any questions or comments, or to otherwise facilitate prosecution of the present application.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By: _____
Joseph D. Kuborn
Reg. No. 40,689

Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, St. 1100
Milwaukee, WI 53202
(414) 271-7590

PTO/SB/01 (07-07)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing **OR** ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	139341-1 (5024-00079)
First Named Inventor	Donald E. Brodnick
COMPLETE IF KNOWN	
Application Number	10/799,297
Filing Date	03/12/2004
Art Unit	3735
Examiner Name	Karen E. Toth

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

RESPIRATION MONITORING SYSTEM AND METHOD

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☑ was filed on (MM/DD/YYYY) 03/24/2004 as United States Application Number or PCT International Application Number 10/799,297 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION — Utility or Design Patent Application

Direct all correspondence to:	☑ The address associated with Customer Number:	73387	OR ☐	Correspondence address below

Name		
Joseph D. Kuborn		
Address		
100 East Wisconsin Avenue, Suite 1100		
City	State	ZIP
Milwaukee	Wisconsin	53202
Country	Telephone	Email
United States	414-271-7590	

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:	☐ A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any])		Family Name or Surname
Donald E.		Brodnick
Inventor's Signature	Donald E. Brodnick	Date 30-Aug-07

Residence: City	State	Country	Citizenship
Cedarburg	WI	US	US
Mailing Address			
N75 W7115 Linden Street			
City	State	Zip	Country
Cedarburg	WI	53012	USA

☑ *Additional inventors or a legal representative are being named on the* 1 *supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.*

PTO/SB/02A (07-07)
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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Scott R	Wiese		
Inventor's Signature Scott R Wiese			Date 9/4/07
Glendale Residence: City	WI State	USA Country	USA Citizenship
1409 N 67th St Mailing Address			
Wauwatosa City	WI State	53213 Zip	US Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Inventor's Signature			Date
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Inventor's Signature			Date
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country